

SEP 26 2000

**510(k) Summary for  
Protein C Reagent**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K002541

**1. Manufacture's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer: Dade Behring Marburg GmbH  
Emil-von-Behring Str. 76  
Marburg/Germany

Contact Information: Dade Behring Inc.  
Glasgow Site  
P.O. Box 6101  
Newark, Delaware 19714  
Attn: Rebecca S. Ayash  
Tel: 302-631-6276

Preparation date: September 11, 2000

**2. Device Name/ Classification:**

Protein C Reagent: Factor Deficiency Test

Classification Number: Class II (864.7320) 81GGP  
7290

**3. Identification of the Legally Marketed Device:**

Protein C Reagent, coagulometric (K924425)

**4. Device Description:**

Protein C in the patient sample is activated by addition of specific snake venom contained in the Protein C Activator Reagent. Activated protein C inhibits Factor V and Factor VIII contained in the added Protein C Deficient Plasma. This inhibition reaction prolongs the subsequent APTT test. The prolongation of the APTT is thus a measure of the protein C content of the patient sample. Graduated dilutions of standard plasma permit a standard curve to be established from which the protein C content of patient samples can be read in percent of norm.

000007

**5. Device Intended Use:**

Protein C Reagent is a coagulation test for the quantitative determination of protein C activity in human plasma.

**6. Medical device to which equivalence is claimed and comparison information:**

There are a number of *in vitro* diagnostic products in commercial distribution, which employ coagulometric techniques for the quantitative determination of protein C activity in human plasma. One such product is the Dade Behring Protein C Reagent, coagulometric assay (K924425). Protein C Reagent is substantially equivalent in intended use and results obtained to the Protein C Reagent, coagulometric assay. The Protein C Reagent, like Protein C Reagent, coagulometric is intended to be used for the quantitative determination of protein C activity in human plasma.

**7. Device Performance Characteristics:**

**Correlation:**

The Protein C Reagent assay was compared to the Protein C Reagent, coagulometric assay by evaluating 86 samples ranging from 11 to 125% of norm. A correlation coefficient of 0.99 was obtained, with a y-intercept value of 4.49 and a slope of 0.91.

**Precision:**

Precision studies were performed by the evaluation of two levels of control material and two levels of human plasma pools in a manner consistent with NCCLS Guideline EP5-A. The intra-assay precision ranged from 1.4 to 2.5%, while the inter-assay precision ranged from 1.1 to 4.7%.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

SEP 26 2000

Ms. Rebecca S. Ayash  
Manager, Regulatory Affairs, Biology  
Dade Behring, Inc.  
Glasgow Site  
P.O. Box 6101  
Newark, Delaware 19714

Re: K002541  
Trade Name: Protein C Reagent  
Regulatory Class: II  
Product Code: GGP  
Dated: August 15, 2000  
Received: August 16, 2000

Dear Ms. Ayash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

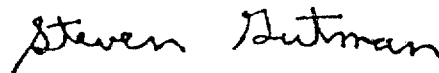
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large, stylized 'S' and 'G'.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

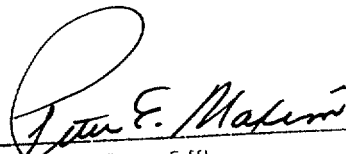
Enclosure

## Indications Statement

**Device Name:** Protein C Reagent

### Indications for Use:

Protein C Reagent is an in vitro diagnostic test for the quantitative determination of Protein C activity in human plasma. Protein C is determined in patients with recurrent thromboembolism and deep venous thrombosis of undetermined etiology as well as differential diagnostic investigation of hemostatic defects, e.g., coumarin-induced necrosis.

  
(Division Sign Off)  
Division of Clinical Laboratory Devices K002541  
510(k) Number \_\_\_\_\_

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

Over-The-Counter-Use ☐  
(Optional Format 1-2-96)